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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,407	11/21/2001	Peter Tam	9050-0048.20	3091

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[REDACTED]

AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
1615	[REDACTED]

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/996,407</b>  Examiner <b>Carlos Azpuru</b>	Applicant(s) <b>Tam et al</b>	Art Unit <b>1615</b>
		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138 (e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1)  Responsive to communication(s) filed on \_\_\_\_\_.
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.
- 4)  Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-11, 15, 24-26, 28-32, 40-43, 45-50, 71, and 72 is/are rejected.
- 7)  Claim(s) 12-14, 16-23, 27, 33-39, 44, and 51-70 is/are objected to.
- 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

- 15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>4</u> | 6) <input type="checkbox"/> Other:  |

## **DETAILED ACTION**

Receipt is acknowledged of the information disclosure statement filed 03/28/02.

### ***Claim Objections***

Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 8 fails to further limit the prior claims since it is clear that the treatment is directed to premature ejaculation during sexual intercourse. Otherwise, the issue would not require treatment, and would not be an issue. No other sexual activity is disclosed or suggested.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 24-26, and 40-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Rowland et al (reference AT).

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Rowland et al disclose the treatment of premature ejaculation by administration of a pharmaceutical composition of clomipramine (see Summary Table 1, pages 890-891, and last paragraph, page 891. Administration in all case studies was accomplished less than an hour prior to ejaculation (see Results/effectiveness heading for all clomipramine studies.) Administration may however occur as much as 4-6 hrs prior (see page 892, lines 1-2) Administration was in the oral form, and may range from 10-50 mg (see page 889, last paragraph). Further, "rapid release" although not expressly disclosed, is indicated since no mention is made of sustained or extended release forms which would teach away from the instant claims. The claims are anticipated by Rowland et al.

Claims 1-11, 15, 24-26, 28-32, 40-43, and 45-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al (reference AH).

Smith et al disclose a method for delaying the onset of ejaculation through the use of various compounds (see Abstract). Antidepressants are among the compounds listed for treatment of premature ejaculation (see col. 3, lines 20-25). And clomipramine is specifically listed at col. 5, line 12. Routes of administration include oral, transmucosal, and oral (see col. 9, lines 39-56). Additional agents for incorporation into the composition and method are listed at col. 11, lines 33-65. Dosage amounts are from 0. to 500 mg (see col. 12, lines 11-13). Although "rapid release" is not expressly disclosed, none of the formulations indicate a sustained or extended release form which would teach away from the instant claims. The instant claims are anticipated by Smith et al.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 71-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowland et al or Smith et al.

Rowland et al disclose the treatment of premature ejaculation by administration of a pharmaceutical composition of clomipramine (see Summary Table 1, pages 890-891, and last paragraph, page 891. Administration in all case studies was accomplished less than an hour prior to ejaculation (see Results/effectiveness heading for all clomipramine studies.) Administration may however occur as much as 4-6 hrs prior (see page 892, lines 1-2) Administration was in the oral form, and may range from 10-50 mg (see page 889, last paragraph). Further, "rapid release" although not expressly disclosed, is indicated since no mention is made of sustained or extended release forms which would teach away from the instant claims.

Smith et al disclose a method for delaying the onset of ejaculation through the use of various compounds (see Abstract). Antidepressants are among the compounds listed for treatment of premature ejaculation (see col. 3, lines 20-25). And clomipramine is specifically listed at col. 5, line 12. Routes of administration include oral, transmucosal, and oral (see col. 9, lines 39-56). Additional agents for incorporation into the composition and method are listed at col. 11, lines 33-65. Dosage amounts are

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from 0. to 500 mg (see col. 12, lines 11-13). Although "rapid release" is not expressly disclosed, none of the formulations indicate a sustained or extended release form which would teach away from the instant claims.

Both references clearly teach the antidepressant composition and method of treating premature ejaculation using said antidepressant composition. While neither reference packages their composition in a kit, the ordinary practitioner would find it well within their skill to do so with the reasonable expectation of obtaining the same therapeutic results suggested by either Rowland et al or Smith et al. Pharmaceuticals are packaged in kits routinely, and since the instant method and compositions are well known in the treatment of premature ejaculation, those of ordinary skill would clearly find it well within their skill to package the claimed invention as is common to any number of pharmaceutical products. The instant claims are obvious in view of the teachings of either Rowland et al, or Smith et al, both of which disclose a clomipramine composition which is administered for its art recognized treatment of premature ejaculation, and the common pharmaceutical practice of packaging pharmaceutical products in kits.

Claims 12-14, 16-23, 27, 33-39, 44, 51-70 are objected to as dependent upon a rejected base claim.

References to Grgis et al (reference AN), and Assalian (reference AL) are also cited for their equivalent teaching of the use of clomipramine in the treatment of premature ejaculation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is 703/308-0237. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

ca  
March 18, 2003



CARLOS A. AZPURA  
PRIMARY EXAMINER  
GROUP 1500